



UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
06/655,897	09/28/84	MARK	D 20832A

ALBERT P. HALLUIN
CETUS CORP.,
1400 58TH ST.,
EMERYVILLE, CA 94608

EXAMINER	
HAZEL, B	
ART UNIT	PAPER NUMBER
127	5
DATE MAILED: 09/04/85	

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|-----------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449 | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152 |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474 | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 44-47, 49-54 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 44-47, 49-54 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☒ This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.
8. ☐ Allowable subject matter having been indicated, formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. These drawings are ☐ acceptable; ☐ not acceptable (see explanation).
10. ☐ The ☐ proposed drawing correction and/or the ☐ proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner, ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved, ☐ disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.
12. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

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The preliminary amendments filed September 28, 1984 and May 20, 1985 have been entered. Claim 53 submitted in the amendment filed May 20, 1985 has been renumbered under 37 C.F.R. 1.126 as claim 54.

Claims 44-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are incomplete in that they depend from cancelled claim 43.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to provide an enabling disclosure. Applicants' invention depends on the use of new plasmids or microorganisms that are not known nor readily available to the skilled artisan. In order to fully satisfy the requirements of the statute a deposit of new microorganisms commensurate in scope with the claims is required. Further, the record must establish that the newly created microorganisms meet the maintenance requirement of M.P.E.P. 608.01(p) part 3.

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Maintenance compliance with Rule 9.1 of the Budapest Treaty or its substance is acceptable.

Claims 44-47 and 49-54 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the above objection to the specification.

Claims 44-46 and 50-54 are rejected under 35 USC 101 and 112, first paragraph, for insufficient proof of utility. Applicants are claiming a myriad of modified IFN- β polypeptides which are alleged to be useful in regulating cell growth in patients, treating patients for viral diseases, and stimulating killer cell activity in patients. Considering the teaching of Sheppard et al. that a single amino acid change in IFN-B abolished its antiviral activity, one skilled in the art is not assured of operability over the wide range claimed. Further there is not found of record any correlation of the in-vitro activity disclosed in the specification with activity in humans.

The references submitted by applicants are made of record. The other references cited were considered in the prosecution of the parent case.

No claim is allowed.

Any inquiry concerning this communication should be directed to B. Hazel at telephone number 703-557-3920.

Hazel:ce

8-29-85

Blondel Hazel
BLONDEL HAZEL
PRIMARY EXAMINER
ART UNIT 127

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